Clinical Trial Management Systems Workspace
Quarterly Meeting
UPMC Cancer Pavilion, Pittsburgh, PA
July 19-20, 2004

AGENDA: MONDAY, JULY 19, 2004 (DAY 1)

MORNING SESSION

- 8:00 AM: Opening Remarks
  - UPCI Director's Welcome (Dr. Ronald B. Herberman)
  - NCICB Welcome (Ken Buetow / Sue Dubman)
  - Meeting Agenda and Logistics (Scott Finley)

- 8:30 AM: Clinical Trials Workspace Strategic Roadmap

- 9:30 AM: Break

- 9:45 AM: Financial-Billing SIG Session

- 11:45 AM: Break

WORKING LUNCH – 12:00 – 1:00

- 12:00 – 12:30: Architecture Working Group Collaboration (Arumani Manisundaram)

- 12:30 – 10:00: Clinical Trials Management: Best Operational Practices & Compliant IT Solutions (Michele Pontinen, MBA)

AFTERNOON SESSION

- 1:00 PM: Break

- 1:15 PM: Structured Protocol Representation SIG Session

- 3:15 PM: Break:

- 3:30 PM: Laboratory Interfaces SIG Session

- 5:30 PM: Adjourn Day 1

AGENDA: MONDAY, JULY 20, 2004 (DAY 2)

Morning Session

- 8:00 AM caBIG Compatibility SIG session
- 10:00 AM: Break
- 10:15 AM: CTMS/CDUS Reporting SIG Session
- 12:15 PM: Break

Afternoon Session

WORKING LUNCH – 12:30 – 1:30 (COINCIDES WITH AE SIG)

- 12:30 PM: Adverse Event Reporting SIG Session
- 2:30 PM: Break
- 2:45 PM: SIG Summary Reports:
  - Financial-Billing (Jill Kuennen)
  - Structured Protocol Representation (Doug Fridsma)
  - Laboratory Interfaces (John Speakman)
  - CTMS/CDUS Reporting (Rhoda Arzoomanian)
  - caBIG Compatibility (Teri Melese & John Speakman)
  - Adverse Event Reporting (Joyce Niland)
- 3:45 PM: Clinical Trials Workspace Roadmap Revisited
- 4:45 PM: Adjourn Day 2

MEETING MINUTES

Introduction

Dr. Douglas Fridsma from The Center for Biomedical Informatics at the University of Pittsburgh Cancer Institute (UPCI) and the host for the CTMS inaugurated the meeting with brief opening remarks, followed by Dr. Ronald B. Herberman (Director, UPCI) and Dr. Kenneth Buetow (Director, NCICB) discussing the importance and relevance of the caBIG project with special reference to clinical trials.

The CTMS workspace coordinator Dr. Scott Finley initiated the working activities beginning with brief introductions from all participants and laying out the strategic roadmap (along with a graphical representation) for the CTMS workspace. The meeting was structured with 2 hr discussions on specialized topics under six separate Special Interest Group (SIG) meetings:

- Adverse Event Reporting SIG
- Compatibility Grading SIG
- CTMS/CDUS Reporting SIG
- Financial Billing SIG
- Laboratory Interfaces SIG
- Structured Protocol Representation SIG

Scott introduced Harshawardhan Bal as a new member of the Booz Allen Hamilton team who would be significantly involved in CTMS related work. An early emphasis on component-based development was stressed as a means to create modules that meshed together to create the complete larger working system. In parallel, the purpose of the discussions was stated to be the generation of requirements that could be turned into Statements of Work (SOW), which would, in turn, drive the development process. An architecture based on HL7 v3.0 messaging was put forth as a way for the individual components of the system to communicate with one another and to achieve an efficient exchange of data at both the syntactic and semantic level. Issues associated with attaining this level of interoperability were discussed, notably that existing (legacy) systems were not yet built to understand HL7 v3.0 based messaging and that a transition period was required before adapters could be created and before the new technology could be implemented in a caBIG compliant manner.

HL7 v3.0 related discussion

- A concern was raised (by Prakash Nadkarni, Yale) that HL7 v3.0 was so radical that it may break systems that attempt to implement the standard.

- Smita Hastak (ScenPro, Inc.) commented that there is an effort to map HL7 v3.0 messages to HL7 v2.x messages so as to achieve backward compatibility.

- Ken Buetow emphasized the importance of converging on the HL7 v3.0 standard to the caBIG participants, saying that major players in the healthcare community including Pharma, commercial software vendors and others were looking to caBIG to

lead the effort in this direction. Significantly, government bodies such as the United States Department of Health and Human Services (DHHS) had made the strategic decision to adopt HL7 v3.0 and therefore, caBIG is well positioned to assume a leadership role in this area.

CTMS components related discussion

- Sue Dubman commented on the Clinical Trials Workspace Strategic Roadmap asking:
    - What were the components of a CTMS?
    - What were the boundaries of the CTMS Workspace? (viz., some hospitals may not consider Financial billing as part of their CTMS)

Also, she said that important aspects of a CTMS such as protocol administration, protocol authoring, registration and status tracking were not present on the graphic.

- Scott summarized Sue's comments and suggested an outline for the initial efforts of the CTMS workspace, starting at the face-to-face meeting:
    - Project 1: What is the scope of the workspace? What are the tasks that are part of this workspace? Or what workspace do the difference tasks belong to? For example, Centers may differ on the financial billing component.

    - Project 2: Define the project-sized components that together comprise the appropriate goals for the clinical trials workspace. The individual pieces and the individual buildable modules then can be turned into SOWs.

- Scott also brought forward the need to achieve standardization in clinical protocols so as to avoid the existence of multiple non-compatible protocols. It was pointed out that it is also important to involve the Pharma companies in the process to ensure that all centers speak the same language and achieve compatibility and a paperless process.

- Deborah Collyar: Protocol review and approval process should be part of the CTMS. She envisioned a bigger role for caBIG in designing, approving, activating and implementing a standardized clinical protocol and helping to streamline the IRB process. She also noted that although specifications for the IRB process were generally available, no guidelines for effective delivery were available.

- Doug Fridsma spoke about the life-cycle of the clinical trials process and mentioned several different areas of interest – who are the users? What is the usage of the CTMS? What are the activities involved?

- Ken Buetow reminded participants to focus on identifying gaps and modify or extend tools that were already available

- John Speakman suggested that in addition to defining and building systems, there is a need to define best practices for clinical institutions to enable the application to be adopted, to attempt to drive change in the way that these institutions operate using an intermediary such as DHHS to push the change

Warren Kibbe commented that the strategic roadmap was a static map and suggested the use of lightweight adapters to enable HL7 messaging

Bob Morrell explained the need to achieve a consistent approach to handling the different types of clinical trials (therapeutic, epidemiological, cooperative trials, industry trials, multi-center trials) and also described his experience with multi-center trials where the different participating centers may not completely agree on definition of the various phases of clinical trials. He added that there was a need to define who the various authorities are that can decide the phases definitively.

Financial billing SIG session

Goals

- Identify the modules or systems to be developed
- Prioritize the identified modules
- Create specifications for each module
- Work with developers to create modules
- Work with adopters to implement modules and return feedback to developers
- Modify specifications for developers
- Continue communications between the adopters, developers and SIG

Steps to take

- Describe the workflow of a cancer center's financial/billing process
- Identify inter-institutional variations of the workflow
- Identify points in the workflow that can be automated
- Determine the specifications of each automated point in the workflow
- Identify if these points can be part of the same system or need stand-alone
- Determine if interfacing with vendor or other homegrown financial systems from these workflow points is possible (i.e., University sponsored programs system)
- Initiate developers and adopters to begin creating modules

Deliverables

- Workflow diagrams
- Checklist of features for existing financial/billing features
- Prioritized list of modules
- High-level specifications of each module

Financial billing SIG meeting minutes (SIG lead: Jill Kuennen)

Some general questions that the SIG tried to address were:

- What modules may comprise a financial billing system for clinical trials?
- What is the scope of such a system?

<u>Workflows</u>

A need to create the workflow for the financial billing process and identify components that can be automated to help improve efficiency was put forward, considering that several cancer centers (including Holden) did not have a financial billing system in place. The system should handle the different types of trials (sponsored trials where a Pharma company is sponsoring the trials and where the research coordinator time or the

procedure performed is billed, and investigator initiated trials which may or may not be sponsored).

Billing
Which things are paid by industry? Insurance? Institutions? It was also important to differentiate between various types of trials – investigator initiated, drug industry initiated etc and be sure that everything is being billed appropriately and paid correctly taking into consideration the high cost of some procedures (for example, MRI). Equally important was to trigger the appropriate messages if a procedure was performed and completed or if there was a need to add a new procedure, for example, a blood draw that was not originally planned in the study.

Standard care vs. research
An important issue was also the differentiation between what in the patient study was being performed as standard care and what was being performed as research and how the different procedures would be covered (by insurance, or the sponsor or, by neither). Associated with the issue of procedures was the concept of the study calendar where the individual procedures to be performed could be specified and defined clearly as standard care or research. The study calendar could also be printed and communicated to the patient to inform the patient about the next visit or upcoming procedures and how they were going to be billed. This also made the job of the nurse coordinator easy since information about procedures was already available thereby facilitating the billing of the procedures as soon as they have been performed.

Study calendar
The study calendar may be created from the study protocol in consultation with the research investigator to understand the procedures involved and the corresponding billing schedules. There was a question whether the study calendar was also capable of handling payment for work done by affiliates. This was currently not implemented at Holden.

Scheduling
A fundamental concern in creating a financial billing system for clinical trials was whether the financial aspect was intimately connected to the scheduling aspect. The scheduling aspect of the CTMS was perceived to be a separate issue although it may feed into the financial billing module because scheduling happens in a clinical setting and can be regarded as a forerunner to the financial aspects. The study calendar of billable procedures was perceived to be part of the clinical protocol while patient and procedure scheduling was regarded as a separate issue (possibly part of financial billing).

Architecture Working group minutes (Arumani Manisundaram)

The architecture workspace was structured into several sub groups that was involved with the following activities:

- APIs, query interface, exposed data/metadata structures, grid service interfaces
- Model, metadata, management, data mappings, ID management, data and model change control

- Runtime technologies, service advertisement, execution of grid queries, messaging, workflow.

- Security/authentication/authorization patient ID, honest broker.

- Software development best practices, tutorials, testing, communications, standards adoption.

The overall goal of the Architecture workspace is to work with the individual domain workspaces to identify user requirements and address specific architecture related needs. Initial prototyping efforts that involved several centers including NCICB were based on open source grid implementations and standards such as the Globus Toolkit (http://www.globus.org/), the Open Grid Services Architecture - Data Access Integration (OGSA-DAI, http://www.ogsadai.org.uk/) and the Mobius Project (http://projectmobius.osu.edu/, Ohio State University) which are involved in the development of tools and middleware components to enable sharing of data and metadata in a distributed computing environment, were described to be successful. Details on the grid technologies, standards used and experience gained from the pilot projects would be posted on the Architecture Workspace Forum for the information of cancer centers.

An important goal of the Architecture Workspace is to obtain a specific well-defined project (including requirements and use cases) from each domain workspace that would serve as a prototype for reference implementation. Ken Buetow mentioned that it was important for the cancer centers to come up with a small project even if it was in early stages of development - the equivalent of the minimal functional “Hello World!” program – to demonstrate proof-of-concept. An up-to-date compendium of software applications that each cancer center has would prove useful in understanding the capabilities of individual centers and would also help the CTMS Compatibility Grading SIG in keeping track of compatibility levels of existing systems and/or their component modules.

Specific examples of reference implementations were discussed (for example, Johns Hopkins Proteomics application). There were questions regarding the criteria that could be used by cancer centers to identify possible reference implementations - the Architecture Workspace would develop an FAQ to define the criteria and distribute it to the domain workspaces. Ken Buetow raised the issue of the difficulty that cancer centers may face over secure transmission of data through firewalls and that this was a critical aspect that should be addressed early on.

Mike Becich forwarded the concept of a “technology petting zoo” where proof-of-concept reference implementations could be demonstrated by cancer centers at face-to-face meetings. He provided the example of the Radiological Society of North America, Inc. (RSNA) who invited the participation of the DICOM (Digital Imaging and Communications in Medicine - the industry standard for transfer of radiologic images and other medical information between computers on a distributed network) standards group at their annual meeting that led to the acceptance of the standard.

Architecture Workspace goals:

- Clarify current description of bronze and silver caBIG compatibility
- Identify existing CTMS or isolated modules to be evaluated (commercial, NCI, Cancer Centers)
- Assemble a group of qualified "evaluators"
- Include member from caBIG Compatibility SIG and NCI Architecture Group
- Make report available to caBIG community

CTMS/CDUS SIG workspace minutes (SIG lead: Rhoda Arzoomanian)

Deliverables for the CTMS/CDUS module for data submission to NCI CTMS/CDUS were discussed. These included development of a regulated reporting interface to submit data electronically to CTMS/CDUS. Data submission to CTMS/CDUS in relation to secure transmission and acknowledgement and limitations of existing systems were discussed. FTP submission was considered a problem because of security issues. Several suggestions (as summarized below by Warren Kibbe, Northwestern Univ.) were put forward.

A data specification for the file format for submission to each system is needed (and for most of these systems is available)

CTMS/CDUS/AdEERS
1. Accept automated electronic data uploads securely - https would be preferred due to the ubiquity of tools available to automate these transfers
   a. a web service would be an early way to approach caBIG goals of discovery and introspection

Handshaking, by priority
1. Give a secure acknowledgement of receipt
2. Give a secure acknowledgement of receipt with byte count
3. Give a secure acknowledgement of receipt that data was validated through a parser
4. Give a secure acknowledgement of receipt that data was validate and patients 1-x were received properly.
5. Give a secure acknowledgement of receipt that data was validated, patients 1-x were received properly, and return a list of errors if errors are encountered

A side recommendation is to make the validation parser (and code for the parser) available to any site so they can perform local validation before submitting to each of these systems.

The publication of a technical contact for each system that would be available to the programmers at the many sites submitting to these systems would be very valuable as well. These communications would be for a very different purpose (programmatic access) than the existing help lines that are currently available for submitting data to these systems.

Any simplification of the file format and integration of CDEs and common vocabularies into data elements required would be of universal benefit to submitters to these services and is consistent with caBIG goals

These are interim recommendations, with the intent that these systems develop a fully caBIG compatible data transmission mechanism at some future point.

Adverse Event Reporting SIG Meeting Minutes (SIG lead: Joyce Niland)

Joyce Niland spoke about the various factors that influence the functionality of the Adverse Event Reporting module. These include the different categories of users (research investigators, sponsors, clinical research personnel, IRBs and the patients themselves, to name a few), the emergence of new standards (HL7, CDISC, ICH, XML ISO, MedDRA, SNOMED, CDE, CTCAE) and regulations (HIPAA, CFR21 Part 11), the organizations that are involved in clinical research in various roles (FDA, NCI DCP, DCPD, CTEP, Theradex, etc.), and existing systems (CDUS, GeMCRIS, AdEERS CSAERS).

The Adverse Event Reporting module was proposed to have the following functionality:

Automated AE Grading, AE Data collection, reporting, alerts for Severe Adverse Events, Routing of AEs, AE repository, vocabulary, management of patient AE, patient self-reporting, public access to AE Information.

A componentized approach to Adverse Event (AE) module development was presented to demonstrate what the different elements (human organizational, regulatory, architectural and data) of the complex system were and how they need to interact and be integrated with one another.

Flow charts for identifying and reporting of adverse events from the perspective of different clinical groups (physician or nurse, principal investigator, Clinical research associate, cooperative group operations center), from the perspective of data handling (Theradex, institutional data management, Pharmaceutical company or cooperative group) and adverse event reporting (to NCI, FDA) were discussed.

Action items

- AE SIG analysis and conference call focused on HL7 Medwatch ballot – Recommend value domain code sets
- Get electronic changes to Activity Diagram from CTEP and complete the CTEP workflow (Ann Setser)
- Obtain rule tables from CTEP for triggering AE reporting
- Discuss SNOMED mapping issues with Vocabulary Workspace
- Follow up on MedDRA licensing issues for future AE modules (including auto-coder)
- Flowchart DCP AE information flow
- Complete domain specific vocabulary analysis, incorporating 70 attributes from Medwatch HL7 ballot

–Incorporate co-morbidities

- Draft optimal idealized workflow for harmonized unified AE reporting module

Michele Pontinen (Booz Allen Hamilton): Clinical Trials Management Systems: Best Operational Practices & Compliant IT Solutions

Michele stressed on the importance of achieving compliance with applicable regulations such as 21CFR part 11 for both cancer centers and the Pharma industry and considering the process of achieving compliance not as a burdensome process but as a part of good practices and as part of an organization's business strategy.

Important in the process of achieving compliance was to view the system as a combination of people and processes and to consider compliance as something that runs through the entire drug development pipeline or the value chain – research, discovery, pre-clinical and clinical studies, manufacturing, distribution and internal management, FDA submissions (IND, NDA, etc.) as well as Phase I-III and IV (post-marketing) studies. The Clinical Trials Management systems that capture, store, analyze, report and share data also need to be validated.

Lab Interfaces SIG meeting minutes (SIG lead: John Speakman)

The Memorial Sloan-Kettering Cancer Center (MSKCC) uses the LCS/SunQuest clinical lab system for storing all its clinical lab results. The information processing model is to import as much lab data as possible on the way into the CTMS (which includes tests and any re-tests done), and filter on the way out. In addition, Memorial Sloan-Kettering Cancer Center also collects all data (not just that collected by CTMS) from a patient as soon as s/he is registered into a protocol beginning 30-days prior to the on-study date. The reason for the 30-day window is that the MSKCC lab system disallows ad hoc querying of data as and when it is needed (to address performance issues). After the patients are first registered into the system, their lab data are transferred to the CTMS system.

Many centers indicated that in contrast to MSKCC collection of patient is discontinued after the patient goes off protocol or after the clinical trial is over. The possible implications of storing all lab data on the patient and collecting that data in a continuous manner even after that patient goes off protocol with respect to HIPAA/IRB issues were discussed. Creation of a best practices document for hospitals or clinical centers to follow was proposed.

Structured Protocol Representation SIG meeting minutes (SIG lead: Doug Fridsma)

The development of a structured protocol representation and understanding the requirements for the development of computable protocols were discussed in relation to the clinical trials life cycle which includes steps like Research protocol development and approval, Pre-trial setup, patient enrollment and management, Reporting and administration, Financial & billing, Statistical Data mining and analysis and New idea generation. Each of these different stages was discussed with respect to users, use

cases and activities that each step involved. This, it was hoped, would result in a structured clinical document (for example, in an HL7 format) as well as a computable representation which could collect and process information from other components such as a financial billing module or adverse events, or other data sources such as clinical research coordinators, as well as allow users to import the information from the system to their respective applications.

Specific use cases and requirements of each of the steps outlined above were discussed. For patient enrollment and management, for example, the need was for patients to be able to find information on their particular type of cancer and search the clinical trials that were available for them to participate in. Similarly, the system should be able to match clinical trials to pathology reports and also provide real time status of open and closed trials for the benefit of the patients. The clinical research coordinators should be able to use the system to determine patient eligibility, track patient throughout the treatment cycles, report adverse events, and identify outcomes and progression in an environment where multiple systems and applications may interact with each other.

Structured nomenclature and vocabulary to capture clinical data was an important aspect of the structured protocol representation because it would allow the various users of the system to record the different pieces of data that are required to be fed into a Clinical Trials Management System.

Automatic eligibility determination: The inclusion and exclusion criteria for participation within a clinical trial can be in the form of an HTML document that can be read by people and transmitted and communicated via a computer. The question was whether a computer can compare the eligibility criteria with the electronic medical record and determine whether or not a patient meets the eligibility criteria. A computable representation of protocol representation should be able to address this need.

Based on the feedback on the life cycle of clinical trials that was obtained during the face-to-face meeting, the SIG would identify best practices and incorporate the experiences and suggestions to define and delineate modules including CDEs that would be part of a Clinical Trials protocol representation and identify and prioritize modeling efforts to achieve that goal. At the same time, use a bottom-up approach to identify use cases and the key elements as well as stakeholders and experts (from the SIG, the Work groups as well as the caBIG community) who can provide information and guidance as the structured protocol representation is created.

The possibility or the need of a collaborative effort between NCI's Clinical Trials Cooperative group program and the caBIG CTMS workspace was discussed. Ken Buetow described the work of the Clinical Trial Working Group (CTWG), a National Cancer Advisory Board (NCAB) reporting group, which is charged with the comprehensive examination of the clinical trials fabric supported by the NCI. The CTWG convenes meetings that are attended by the Cooperative groups and CTEP and is involved in identifying gaps in the existing clinical trials management systems, processes or research and defining actionable steps that can address problems in the short and long term (weeks to months). In addition, it is also considering technical aspects such as the nature or make up of CTMS architecture and infrastructure and in relation to that,

caBIG would be considered as part of that effort, except that caBIG would involve a community wide effort.

Compatibility Grading SIG minutes (SIG leads: Teri Melese, John Speakman)

The need to clearly define the criteria for caBIG compatibility at the bronze, silver and gold level in cooperation with the Architecture workspace was expressed. At the same time, the need to identify experts within cancer centers in the area of software evaluation that would form a review body and the development of a suite of validation tests to assess existing systems for caBIG compatibility was felt. A full-scale professional life cycle evaluation that would include evaluation of design processes used to develop the software was suggested. The development of compatibility guidelines would be a collective community driven process and would welcome suggestions and participations from all groups including commercial vendors.

The nature of the review process – whether it should be conducted at the level of a single module or at the level of the whole system – was discussed. A score based system to enable a finer grading of systems was suggested - for example, a numerical value which would be mapped to bronze, silver or gold level or a subset thereof based on the number of modules in a system and the proportion of modules that a system has in each of the three categories - but it was not perceived to be necessary. It was generally accepted that the overall caBIG compatibility level of a given software package would be the lowest compatibility level of its component modules.

The issue of evaluation of functionality in relation to the evaluation of compatibility and interoperability was raised given the fact that it was possible to have systems that were interoperable but not functional. Again, it was felt that the Architecture Workspace should define what compatibility and functionality means from an architectural point of view. The best practices subgroup of the Architecture workspace would work closely with the CTMS workspace to define the underlying architecture for achieving compatibility and functionality. One of the important goals of the Architecture Workspace is to identify grid standards and to provide proof of concept with the caGRID based on the Globus toolkit, the Open Grid Services Architecture Data Access and Integration (OGSA-DAI) framework and The Ohio State University Mobius Project. The Architecture workspace would also evaluate the needs and use cases arising from the various domain workspaces and identify reference implementations that can address the issues that surface during these two projects.

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